

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED ASSOCIATION OF PLUMBERS &
PIPEFITTERS LOCAL 322 OF SOUTHERN
NEW JERSEY,
*on behalf of itself and
all others similarly situated,*

Plaintiffs,

v.

MALLINCKRODT ARD LLC;
MALLINCKRODT PLC; CIGNA HOLDING
COMPANY; CIGNA CORPORATION;
EXPRESS SCRIPTS HOLDING COMPANY;
EXPRESS SCRIPTS INC.; CURASCRIPT
INC.; CURASCRIPTS SD; PRIORITY
HEALTHCARE CORP.; PRIORITY
HEALTHCARE DISTRIBUTION, INC.;
ACCREDITO HEALTH GROUP, INC.;
UNITED BIOSOURCE CORPORATION; *and*
LISA PRATTA,

Defendants.

Civil Action Number: 1:20-cv-00188

Judge Robert B. Kugler

**MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S
MOTION TO DISMISS CLASS ACTION COMPLAINT AND MOTION TO STRIKE**

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I. INTRODUCTION

This is the sixth case and third class action in which Plaintiff’s lead counsel represents a third-party payor (“TPP”) of prescription drug benefits who complains about the price of the specialty pharmaceutical Acthar® Gel (“Acthar®”). The obvious reason for that price is the drug’s value as the *admitted* “gold standard” for treating less than 2,000 instances of infantile spasms (“IS”) each year, and as a last line of treatment for other conditions. Class Action Complaint (“Cmplt.”) ¶¶ 120, 140. To suggest otherwise, Plaintiff’s counsel recites a sprawling narrative that disparages as an unlawful “scheme” nearly every Acthar® distribution, pricing and marketing decision ever made by Questcor Pharmaceuticals, Inc. (“Questcor”) after purchasing the rights to Acthar® in 2001 and by Mallinckrodt ARD LLC (“Mallinckrodt”) after purchasing Questcor in 2014. The narrative, however, repeatedly mischaracterizes lawful conduct as an unlawful “scheme,” offers overreaching generalizations, and fails to connect any alleged misconduct to the *one* Acthar® prescription that Plaintiff alleges it covered.

Because of similar failings, two federal district courts have already dismissed in whole or in part TPP cases brought by Plaintiff’s counsel asserting similar claims. *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019); *Washington Cty. Bd. of Educ. v. Mallinckrodt ARD, Inc.*, No. CV JKB-19-1854, 2020 WL 43016 (D. Md. Jan. 3, 2020). Both courts dismissed all RICO and related common-law claims that were similar to those asserted here. Two other courts denied motions to dismiss such claims without an opinion. Order, *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC*, No. 19-cv-03047 (E.D. Pa. Dec. 19, 2019); Order, *Int’l Union of Operating Engineers Local 542 v. Mallinckrodt ARD, LLC*, No. 2018-14059 (Pa. Commw. Ct., Montgomery Cty. Jan. 8, 2019). The court in *Rockford* did allow antitrust claims

similar to those asserted here to go forward, but for the reasons stated below, Mallinckrodt urges the Court not to do so in this case.

Plaintiff's claim under the New Jersey Antitrust Act rests on three theories, each of which fails to plausibly allege essential elements, requiring dismissal of the claim:

- **Exclusive Distribution.** Plaintiff alleges that Questcor's agreement making Defendant CuraScript the exclusive distributor for Acthar[®] is an "unreasonable" restraint of trade. But such vertical agreements are presumptively reasonable and lawful. Questcor, as the only owner and manufacturer of Acthar[®], had the lawful authority to unilaterally set the drug's price and output, regardless of the number of distributors it used.
- **Vertical Agreements about Price.** Plaintiff alleges that Questcor conspired with Defendant Express Scripts, Inc. ("Express Scripts"), the pharmacy benefits manager ("PBM") for Plaintiff and other TPPs, to raise the price of Acthar[®]. But the Complaint contains no allegations "tending to exclude the possibility" that Questcor acted unilaterally when raising the price of the drug. Plaintiff also alleges a vertical price-fixing agreement between Questcor and its distributor CuraScript. But that theory falls flat for several reasons, including that Plaintiff later alleges that Questcor sold Acthar[®] through CuraScript on "consignment," an arrangement that would lack an antitrust "agreement" on price.
- **Synacthen Acquisition.** Plaintiff alleges that Questcor's 2013 acquisition of the rights to Synacthen Depot ("Synacthen") from Novartis AG was an attempt to maintain a monopoly for Acthar[®] in violation of the New Jersey Antitrust Act. Plaintiff, however, fails to allege facts that would plausibly indicate that it has suffered antitrust injury—by paying higher prices for Acthar[®]—as a result of that acquisition. Mallinckrodt has since divested and sublicensed its Synacthen rights, yet Plaintiff does not plead that Synacthen is now or will soon be on the market, a failure which renders Plaintiff's theory of harm speculative.

Beyond these fatal flaws, Plaintiff also has failed to plead a plausible relevant antitrust market: It has proposed one that includes only Acthar[®], while admitting that Acthar[®] faces competition from cheaper alternatives for many of its indications. This failure is an independent basis for dismissal.

Plaintiff's New Jersey RICO claim, which is predicated on alleged mail and wire fraud, also fails for several reasons:

- As explained in *Washington County*, the supposed "schemes" either do not involve any misrepresentation or actionable omission by Mallinckrodt or do not identify one with the particularity required by Rule 9(b). Plaintiff's claim rests on a false premise that high prices or a failure to disclose the pricing rationale is fraud.

- Plaintiff fails to allege facts that would transmute “run-of-the-mill” business activities among Mallinckrodt and those involved in the distribution and sale of Acthar[®] into a RICO enterprise.
- Plaintiff has failed to allege any connection between its alleged injury and Mallinckrodt’s alleged conduct. For example, Plaintiff asserts claims based on “off-label” promotion without alleging that its one beneficiary to whom Acthar[®] was prescribed received the prescription for “off-label” use.

Plaintiff’s claim under the New Jersey Consumer Fraud Act (“CFA”) and common-law negligent misrepresentation fail for the same reasons as the RICO claims and for the further independent reasons that: (a) Plaintiff did not itself use Acthar[®] and thus lacks standing under the CFA under *any theory* because it is not a consumer; (b) Plaintiff’s claim is based on pharmaceutical marketing, which is pervasively regulated by the FDA and, therefore, not actionable under the Act under *any theory*; and (c) a negligent misrepresentation claim requires “reliance,” yet Plaintiff expressly disclaims knowledge of any false statement when alleging it “would not have paid and/or reimbursed the artificially inflated prices for Acthar[®] *had it known of the [alleged] false representations . . .*” Cmplt. ¶ 665 (emphasis added).

Finally, Plaintiff’s conspiracy and unjust enrichment claims fail because neither is a standalone claim under New Jersey law and due to the numerous flaws discussed above.

II. BACKGROUND

A. Acthar, Questcor, and Mallinckrodt

Acthar[®] is an adrenocorticotrophic hormone (“ACTH”) product that is injected intramuscularly. *See id.* ¶¶ 3, 5, 64, 463. The FDA first approved it in 1952. *See id.* ¶ 63. By the 1960s, “[i]njectible ACTH medications faced a variety of competing products.” *Id.* ¶ 113. By 2001, Acthar[®]’s manufacturer, Aventis Pharmaceutical Products Inc. (“Aventis”), made so little on the drug (*id.* ¶ 114) the supply of the drug was in jeopardy.

In July 2001, Questcor Pharmaceuticals, Inc. (“Questcor”) acquired Acthar® from Aventis. *Id.* ¶ 4. Questcor thereafter embarked on a “new strategy” for Acthar®. *Id.* ¶ 7. Unlike most prescription medications that are sold in retail pharmacies, Acthar® is a “specialty pharmaceutical” that is distributed through “specialty pharmacy distributors” and “specialty pharmacy providers.” *Id.* ¶ 5. In June 2007, Questcor announced that it had entered into an exclusive distribution agreement with CuraScript, a specialty pharmacy distributor owned by Express Scripts. *Id.* ¶¶ 45, 163. CuraScript sells Acthar® to a total of 10 specialty pharmacies, each of which sells Acthar® to payors. *See* Cmplt. ¶¶ 194–199 & Figure 2. One of those 10 specialty pharmacies is Defendant Accredo Health Group, Inc. (“Accredo”), which is also owned by Express Scripts. *See id.* ¶ 49, 194.

Questcor engaged Defendant United BioSource’s predecessor (“UBC”) to act as its “HUB” for a new program called the “Acthar Support and Access Program,” or “ASAP.” *Id.* ¶¶ 6, 10, 154, 163, 180. The ASAP Program makes use of an “Acthar Start Form.” Among other things, the Acthar Start Form requires the patient and the prescribing physician to certify that the prescription is “medically necessary.” *Id.* ¶ 187. Physicians are directed to complete and transmit the Start Form to UBC. *See id.* ¶ 184. UBC “confirms the prescription by the provider and the associated specialty pharmacy, and then confirms the patient’s insurance coverage or other source of payment.” *Id.* ¶ 185. UBC also provides “patient assistance and access programs, medication shipment tracking, and home injecting training.” *Id.* ¶ 189.

As part of the “new strategy,” Questcor also pursued an “orphan drug” pricing strategy. *Id.* ¶ 174. Acthar® is the “gold standard” for treating IS, a rare but serious condition in infants; but in 2007, Acthar® still had not received FDA approval for that indication. *Id.* ¶ 140. Starting in August 2007, Questcor pursued FDA approval for IS, and in 2010, the FDA approved Acthar® for

IS and granted it “orphan drug status.” *See id.* In August 2014, Defendant Mallinckrodt plc acquired Questcor, which became Mallinckrodt ARD. *Id.* ¶ 33–35.

B. Plaintiff’s Claims

Plaintiff asserts seven claims for relief against Mallinckrodt, all under New Jersey law: statutory claims under the New Jersey Consumer Fraud Act (Count I), the New Jersey Antitrust Act (Count II), and the New Jersey RICO Act (Counts III and IV); and the common law doctrines of negligent misrepresentation (Count V), conspiracy/aiding and abetting (Count VI), and unjust enrichment (Count VII).

Plaintiff’s claims are premised on alleged conduct categorized by under three alleged “schemes” involving Acthar®: a “Distribution Scheme”, a “Pricing Scheme”, and a “Marketing Scheme”. Cmpl. ¶¶ 9–20. The participants in these schemes allegedly were Questcor (later Mallinckrodt ARD) and the “Cigna/Express Scripts” Defendants—Defendant PBM Express Scripts, which was acquired by Cigna Corporation in 2018, and its subsidiaries, Defendants CuraScript, UBC, and Accredo. Cmpl. ¶¶ 1, 4, 6, 10, 38–39, 51, 54–56.

Alleged Distribution Scheme. Plaintiff alleges that Questcor and later Mallinckrodt limited the distribution of Acthar® to just one specialty pharmacy distributor, CuraScript, and engaged UBC to act as its exclusive “HUB.” *See id.* ¶ 10. Plaintiff alleges that the purpose of the exclusive agreements was to control and limit output, and to raise the price of Acthar®. *Id.*

Alleged Pricing Scheme. Plaintiff alleges that Questcor and Mallinckrodt “manipulated and inflated” the price paid by TPPs for Acthar® in three ways. *First*, Plaintiff alleges that Mallinckrodt agreed with CuraScript and UBC to raise the average wholesale prices (“AWPs”) paid for Acthar®, and more generally, that Questcor and the Defendants engaged in a scheme to

raise prices of Acthar[®] to supracompetitive levels. *See id.* ¶¶ 10, 13, 598, 615. Plaintiff further alleges that Defendants did not disclose the “real reasons” for the price increases. *See id.* ¶ 222.

Second, Plaintiff alleges that Questcor and Mallinckrodt misrepresented the price of Acthar[®]. Plaintiff and other payors have “used the AWP’s published in pharmaceutical industry publications, such as the Red Book and Medispan, for years as a basis for reimbursement, in whole or in part.” *Id.* ¶ 242. Plaintiff alleges that “[t]hese publications set forth the false AWP’s for Acthar[[®]], as reported with each price change by Mallinckrodt.” *Id.* ¶ 243. Plaintiff further alleges that, in 2018, Mallinckrodt issued a press release in response to the filing of litigation relating to Acthar[®] that misrepresented the price of Acthar[®]. *See id.* ¶¶ 233–39.

Third, Plaintiff alleges that Questcor’s 2013 acquisition of the exclusive rights to develop, market, and sell assets to Synacthen, a synthetic ACTH product, was anticompetitive. *Id.* ¶¶ 518–522. Plaintiff’s claim regarding Synacthen is based on a Federal Trade Commission (“FTC”) complaint, *see id.* ¶ 523, in a matter which Mallinckrodt agreed to settle in 2017 without admitting any wrongdoing.¹

¹ Plaintiff’s allegations regarding the FTC and other settlements are improper and should be stricken from the complaint under Rule 12(f). The settlement agreements are inadmissible, *see* N.J. R. Evid. 408, and such agreements should be stricken from the complaint as immaterial as they are “not the result of an actual adjudication of any of the issues,” *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976) (holding that consent judgment with the SEC must be struck from the complaint). None of the settlements alleged is based on an adjudication or admission of liability. Stipulated Agreement at 8, *FTC v. Mallinckrodt ARD Inc. et al.*, No. 1:17-cv-00120 (D.D.C. Jan. 18, 2017), ECF No. 2-1 (“Order does not constitute evidence against the Defendants or any admission of liability or wrongdoing by Defendants.”); Settlement Agreement at 3, *United States ex rel. Strunck v. Mallinckrodt ARD*, No. 2:12-cv-00175-BMS (E.D. Penn. Sept. 20, 2019), ECF No. 74-1 (“The Settlement Agreement is neither an admission of liability by Questcor nor a concession by the United States that its claims are not well founded.”); Stipulation of Dismissal of Action with Prejudice at 2, *Retrophin, Inc. v. Questcor Pharmaceuticals, Inc.*, 8:14-cv-00026 (C.D. Cal. June 4, 2015), ECF No. 65 (stipulating that claims be “dismissed with prejudice, without any admission of liability”).

Alleged Marketing Scheme. Plaintiff alleges that “[t]he Marketing Scheme in this case is identical to the scheme alleged in the Strunck & Pratta and Clark Complaints [the *qui tam* complaints], and as amended in the U.S. Complaint in Intervention” with the only difference being that the “affected class” is one of private payors, as opposed to government payors. *Id.* ¶ 263.

Plaintiff, however, blurs the limited nature and duration of the conduct alleged in those actions to broadly generalize about a supposed “Marketing Scheme” with three components. *First*, Plaintiff alleges that, as part of the new strategy in 2007, Questcor hired “Medical Science Liaisons” or “MSLs” to promote Acthar® for off-label uses. *See id.* ¶¶ 20, 266–70. Plaintiff also alleges that Questcor paid doctors known as “Key Opinion Leaders” or “KOLs” to generate clinical data to support the use of Acthar® for off-label uses. *See id.* ¶¶ 272–74. The allegations in the *qui tam* actions more specifically allege this activity in relation to “off label uses to patients who have the progressive form of [multiple sclerosis (“MS”)] through a practice known as ‘pulse’ therapy, even though it is only indicated for acute exacerbations or relapses” of MS. Fourth Amended Qui Tam Complaint at ¶ 33, *United States ex rel. Strunck v. Mallinckrodt ARD LLC*, No. 12-cv-00175 (E.D. Pa., June 13, 2017), Dkt. 40.

Second, Plaintiff alleges that the payments from Questcor (and later Mallinckrodt) to KOLs were bribes meant to incentivize those doctors to prescribe Acthar®. *Cmplt.* ¶¶ 15, 388, 426. The government alleged that twelve Questcor sales representatives reimbursed expensive meals and entertainment for doctors between 2009 and 2013.²

Third, Plaintiff alleges that to prevent patient complaints about high co-pays, Questcor created a Patient Assistance Program (“PAP”) that subsidized patient co-pays. *See id.* ¶¶ 15, 379.

² U.S. Department of Justice, Press Release No. 19-928 (September 4, 2019) (available at <https://www.justice.gov/opa/pr/drug-maker-mallinckrodt-agrees-pay-over-15-million-resolve->

On this topic, the government alleges that, from 2010 to 2014, Questcor illegally paid co-payment subsidies to Medicare patients through a foundation called the Chronic Disease Fund (“CDF”). Complaint in Intervention at ¶ 5, *United States ex rel. Strunck v. Mallinckrodt ARD LLC*, No. 12-cv-01776-BMS (E.D. Pa. June 4, 2019), Dkt. 57.

C. Plaintiff’s Alleged Purchase of Acthar®

Plaintiff alleges that in 2018, it paid \$26,100.28 for a single Acthar® prescription. Cmpl. ¶¶ 21, 29. Plaintiff alleges that the prescription was written for a rheumatic disorder. *See id.* ¶¶ 111, 357. Plaintiff does not allege that the prescription was for an off-label use, that its plan required its beneficiary to pay a co-payment, or that its beneficiary received assistance from any “patient assistance program.”

III. LEGAL STANDARDS

On a motion to dismiss, the Court must assume the veracity of well-pleaded factual allegations and determine “whether they plausibly give rise to an entitlement for relief.” *Ashcroft v. Iqbal*, 556 U.S. 662 (2009)); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The plaintiff must allege the means through which a defendant supposedly acted unlawfully, “details confirming those means, and alleged facts connecting those means to [the plaintiff’s] own injuries” *See Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 776 (3d Cir. 2018) (citations omitted). The Court does not have to accept as true “unsupported conclusions and unwarranted inferences,” or legal conclusions. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997).

Under Rule 9(b)’s heightened pleading requirement, a party alleging fraud “must state with particularity the circumstances constituting fraud” Fed. R. Civ. P. 9(b). *See In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002). Generalized allegations of fraud

alleged-false-claims-act-liability). This statement is judicially noticeable for the fact of the government’s allegations under Fed. Rule Evid. 201(b)(2).

are insufficient; rather, to withstand scrutiny on a motion to dismiss, a complaint alleging fraud must plead (among other things) “the who, what, when, where and how of the events at issue” with particularity. *U.S. ex rel. Moore & Co. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) (quoting *In re Rockefeller Ctr Props.* 311 F.3d at 217).

IV. ARGUMENT

A. Plaintiff Fails to State a Claim under the New Jersey Antitrust Act (Count II)

Like the federal Sherman Act, New Jersey’s Antitrust Act prohibits (a) agreements that “unreasonably” restrain trade in any relevant market, N.J.S.A. 56:9-3; *State v. Lawn King, Inc.*, 404 A.2d 1215, 1216–17 (N.J. Super. Ct. App. Div. 1979), and (b) the acquisition or maintenance of a monopoly in any relevant market through anticompetitive conduct, N.J.S.A. 56:9-4(a); *Patel v. Soriano*, 848 A.2d 803, 829–30 (N.J. Super. Ct. App. Div. 2004). Private parties may supplement government enforcement of the Act only if they have suffered or are threatened with a resulting injury that is of the type the antitrust laws aim to prevent. N.J.S.A. 56:9-10(b), 56:9-12; *see Monmouth Real Estate Inv. Trust, Manville Foodland, Inc.*, 482 A.2d 186, 191 (N.J. Super. Ct. App. Div. 1984). These provisions are interpreted “in harmony with ruling judicial interpretations of comparable Federal antitrust statutes.” N.J.S.A. 56:9-18; *Lawn King*, 404 A.2d at 1216 (internal quotation and citation omitted).

Plaintiff’s claim under the New Jersey Antitrust Act fails to state a claim and must be dismissed because (1) each of its three theories of anticompetitive conduct lack essential elements that must be alleged at the pleading stage and (2) all of its theories are predicated on an implausible definition of the relevant antitrust market.

1. Each of Plaintiff's Antitrust Theories Fails to Allege Anticompetitive Conduct or Non-Speculative Antitrust Injury

a. Mallinckrodt's Exclusive Distribution Agreement Is Presumptively Procompetitive

To survive a motion to dismiss Plaintiff's conclusory allegation that Mallinckrodt's exclusive distribution agreement with CuraScript is an unreasonable restraint of trade must be supported by allegations of fact making plausible a net harm to the competitive process. In contrast to certain agreements among competitors, agreements between firms that work together in the chain of distribution for a product, so-called vertical agreements, are not subject to any *per se* rule of illegality. *E Z Sockets, Inc. v. Brighton-Best Socket Screw Mfg. Inc.*, 304 A.2d 1364, 1367 (Ch. Div. 1996), *aff'd*, 704 A.2d 1309 (App. Div. 1997) (citing *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 97 S.Ct. 2549, 53 L.Ed.2d 568 1977)). As first recognized in *GTE Sylvania*, those agreements "have a real potential to stimulate interbrand competition," which is competition between different manufacturers' products and is distinct from "intrabrand" competition among distributors of the same manufacturer's product. 304 A.2d at 1367. Specifically, "manufacturers can use [vertical restraints] to induce" downstream sellers to, among other things, provide additional services that affect "a manufacturer's goodwill and the competitiveness of his product," and that "might not be provided by retailers in a purely competitive situation" due to "market imperfections such as the so-called 'free rider' effect." *GTE Sylvania*, 433 U.S. at 54–55.

Because interbrand competition is the "primary purpose of the antitrust laws" these benefits will outweigh any impairment to intrabrand competition and leave the vertical restraint reasonable. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 890 (2007). As such, "vertical exclusive distributorships . . . are presumptively legal." *Republic Tobacco Co. v. North Atlantic*

Trading Co., Inc., 381 F.3d 717, 736 (7th Cir. 2004).³ And courts routinely dismiss antitrust claims challenging exclusive distribution agreements for failure to allege facts that would plausibly show harm to competition.⁴

Not only has Plaintiff failed to plead any facts overcoming this presumption of legality, but the facts that it does allege about the downstream distribution channel for Acthar[®] describe procompetitive benefits from the exclusive distribution relationship. Participants in the distribution chain provide precisely the type of additional services that the U.S. Supreme Court contemplated in *GTE Sylvania*: “Upon receipt of the Acthar Start Form, UBC confirms the prescription by the provider and the associated specialty pharmacy, and then confirms the patient’s insurance coverage or other source of payment.” Cmpl’t. ¶ 185. UBC ensures a form of payment before requesting shipment of the drug so as to reduce the risk waste. *Id.* ¶ 191. In addition to “reimbursement and coverage support,” UBC provides “patient assistance and access programs, medication shipment tracking, and home injecting training.” *Id.* ¶ 189. This includes “‘Home Injection Training Services’ . . . by which Mallinckrodt pays to have a nurse visit the patient teach them [sic] how to self-inject the Acthar.” *Id.* ¶ 201.

Plaintiff’s allegation that “Mallinckrodt created this exclusive distribution arrangement to limit and control distribution and output of Acthar[®]], and to raise the prices of Acthar[®]] to

³ See also *Electronics Commc’ns Corp. v. Toshiba Am. Consumer Prods.*, 129 F.3d 240, 245 (2d Cir. 1997) (“[E]xclusive distributorship arrangements are presumptively legal.”); *Crane & Shovel Sales Corp. v. Bucyrus-Eric Co.*, 854 F.2d 802, 807 (6th Cir. 1988) (holding that a manufacturer’s change of distributors does not state a claim unless it alleges anticompetitive effect at the interbrand level).

⁴ See, e.g., *E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass’n, Inc.*, 357 F.3d 1, 8–9 (1st Cir. 2004) (affirming dismissal of complaint with prejudice); *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 734–36 (9th Cir. 1987) (affirming dismissal of complaint by reasoning that “an agreement between a manufacturer and a distributor to establish an exclusive distributorship is not, standing alone, a violation of antitrust laws, and in most circumstances does not adversely affect competition in the market”).

unconscionable levels,” Cmplt. ¶ 10, misapprehends basic economics and applicable law. The central plank of Plaintiff’s Complaint is that, as the sole manufacturer of Acthar®, Mallinckrodt is a monopolist in the market for the sale of “ACTH drugs.” *Id.* ¶¶ 3, 469–70. An exclusive distribution arrangement “provides no monopolistic benefit to [a monopolist] that it does not already enjoy.” *E&L Consult., Ltd v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2nd Cir. 2006). As the court in *E&L Consulting* explained when it rejected the contention (like Plaintiff’s here) that an exclusive distribution agreement left end users with fewer purchase options and “artificially inflated prices”: “the alleged single source [distribution] and price increase, even if monopolistic, is something [the manufacturer] can achieve without the aid of a distributor.” *Id.* at 30. Consistent with *E&L Consulting*, courts have dismissed antitrust claims premised on an alleged monopolist’s exclusive arrangements on the ground that such agreement cannot plausibly harm competition.⁵

The court in *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019), recognized the above principles, but concluded that they were not determinative because the plaintiff there, like Plaintiff here, alleged that the exclusive distributorship and Mallinckrodt’s purchase of Synacthen rights were both acts in furtherance of a larger conspiracy between Mallinckrodt and Cigna/Express Scripts entities to raise the price of Acthar® to supra-competitive levels. *Id.* at 753–55. We respectfully disagree with the reasoning of *Rockford* for two reasons. *First*, while all acts in furtherance of a scheme that may be anticompetitive should be considered

⁵ *E.g., CAE Inc. v. Gulfstream Aerospace Corp.*, 203 F. Supp. 3d 447, 454-55 (D. Del. 2016) (dismissing Sherman Act claim because “Gulfstream’s exclusive arrangement with FSI does not result in any greater anticompetitive effect than would be present if Gulfstream had elected to develop its *own* flight simulator”); *VBR Tours, LLC v. Nat’l R.R Passenger Corp.*, No. 14-cv-804, 2015 WL 5693735, at *12-13 (N.D. Ill. Sept. 28, 2015) (dismissing Sherman Act claim based on exclusive agreement between Amtrak and tour operator because Amtrak “could have accomplished the same effect” on its own); *Spinelli v. NFL*, 96 F. Supp. 3d 81, 116 (S.D.N.Y. 2015) (dismissing Sherman Act claim because the effect of an exclusive license “is something that the [defendant] can legally achieve without the aid of a licensee”).

“as a whole” in assessing whether a scheme is anticompetitive, *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962), the facts alleged by Plaintiff describe conduct that has no net anticompetitive effect and therefore cannot be considered with other acts to establish a violation.⁶ *Second*, Plaintiff’s allegations that Cigna/Express Scripts entities conspired with Mallinckrodt to raise Acthar[®]’s price fail for the reasons stated below.

b. Allegations of Vertical Agreement to Raise Prices Fail under *Monsanto*, *Copperweld* and *Leegin*

Plaintiff’s convoluted theory that Cigna/Express Scripts entities, whose business it is to reduce the cost of pharmacy benefits, conspired with Mallinckrodt to raise the price of Acthar[®] to supracompetitive levels defies accepted principles of economics. The theory also runs headlong into three well-established antitrust doctrines, each of which is sufficient to dismiss the antitrust claims.

(1) Plaintiff’s allegations fail under *Monsanto Co. v. Spray-Rite Service Corp.*, 465 U.S. 752 (1984), to plausibly allege that the Cigna/Express Scripts entities conspired with Mallinckrodt to raise the price of Acthar[®]. *Monsanto* articulates the substantive and evidentiary standard to reasonably infer such an agreement:

The correct standard is that there must be evidence that tends to exclude the possibility of independent action by the manufacturer and distributor. That is, there must be direct or circumstantial evidence that reasonably tends to prove that the manufacturer and others had a conscious commitment to a common scheme designed to achieve an unlawful object.

⁶ *In re Independent Serv. Orgs. Antitrust Litig.*, 989 F. Supp. 1131, 1134 (D. Kan. 1997), *aff’d*, 203 F.3d 1322 (Fed. Cir. 2000) (observing that conduct expressly authorized by law cannot, by virtue of *Continental Ore*, be transformed into unlawful conduct simply because such conduct is alleged to be part of a scheme to monopolize); *California Computer Prods., Inc. v. IBM*, 613 F.2d 727, 746 (9th Cir. 1979) (holding that no “synergistic result” can arise from “acts constitut[ing] reasonable, pro-competitive conduct for a monopolist”); *Southern Pac. Comm. Co. v. AT&T*, 556 F. Supp. 825, 888 n.69 (D.D.C. 1983) (“[O]nce a claim is found to be without merit, such a claim cannot be used as a basis for finding other claims to constitute a violation of the antitrust laws because treating such claims collectively ‘can have no synergistic effect.’”).

465 U.S. at 768. Thus, to state a claim, Plaintiff’s allegations “must include evidence tending to exclude the possibility of independent action.” *Twombly*, 550 U.S. at 554; *see also Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 216, 226 (3d Cir. 2011) (affirming dismissal).

Plaintiff alleges no direct evidence of the conspiracy about which it speculates. Rather, Plaintiff offers only the conclusory allegation that “Mallinckrodt and Cigna/Express Scripts agreed in writing to raise the prices of Acthar[®] to supracompetitive levels.” Cmpl’t. ¶ 617. The allegation is insufficient to constitute an allegation of direct evidence of a conspiracy. *See, e.g., Burtch*, 662 F.3d at 225–26 (affirming dismissal of conspiracy claim because, in part, complaint did not allege direct evidence of a conspiracy where “none of [the complaint’s] allegations specify a time or place that any actual agreement . . . , nor do they indicate that any particular individuals or [defendants] made such an agreement”).

Nor does Plaintiff plead any circumstantial evidence that plausibly “tends to exclude the possibility of independent action by [Mallinckrodt].” *Monsanto*, 465 U.S. at 768. Most critically, Plaintiff pleads no facts plausibly suggesting that Cigna/Express Scripts entities had any rational economic motive to inflate the price of Acthar[®], given that they are in the business of reducing the price that their clients pay for prescription drugs. Because the Cigna/Express Scripts entities “had no rational economic motive to conspire, [] if their conduct is consistent with other, equally plausible explanations, the conduct does not give rise an inference of conspiracy.” *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 596–97 (1986); *Burtch*, 662 F.3d at 229. The Cigna/Express Scripts entities’ alleged conduct is consistent with another equally plausible explanation: that they acquiesced in Mallinckrodt’s unilateral price increases. A distributor’s acquiescence in a course of conduct by a manufacturer does not constitute “‘a meeting of the minds’ or ‘a common scheme’” between the two. *Monsanto*, 465 U.S. at 764 n.9.

(2) A key component of Plaintiff's theory is its speculation that Mallinckrodt "'consigns' the Acthar[®]] to Cigna/Express Script's CuraScript." Cmplt. ¶ 191. But this speculative allegation strips any vertical-price-fixing theory of the required "agreement" as that element is defined by *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984). Under the *Copperweld* doctrine, a corporation's coordination with its affiliates, officers, employees, or *agents* "must be viewed as that of a single enterprise" for purposes of the "agreement" or "conspiracy" element of an antitrust violation. *Id.* at 669, 771; *Petrocco v. Dover General Hosp. & Med. Cntr.*, 642 A.2d 1016, 1028 (N.J. Super. Ct. App. Div. 1994) ("a hospital is incapable of conspiring with its staff in deciding whether to grant staff privileges" under N.J.S.A. 56:9-3). A distributor or retailer who sells a manufacturer's product under a genuine consignment arrangement acts as the manufacturer's agent in the sale and, thus, does not enter into a price-fixing conspiracy when charging a price selected by the manufacturer. *Day v. Taylor*, 400 F.3d 1272, 1277–78 (11th Cir. 2005) (dismissing complaint for alleged vertical price fixing for lack of "agreement" where a consignment arrangement left the manufacturer with the risk of loss); *see also United States v. General Electric Co.*, 272 U.S. 476, 488 (1926). Here, Plaintiff alleges that Mallinckrodt sells Acthar[®] to patients and TTPs in precisely that manner: "Mallinckrodt remains at risk for the sale of the product until it is shipped. Mallinckrodt maintains all right, title and interest to the Achar until it is approved for delivery by Cigna/Express Scripts' UBC to the patient and payment is assured by the TPP." Cmplt. ¶ 191. Under Plaintiff's own allegations, Mallinckrodt and CuraScript are incapable of conspiring to set the price at which Acthar[®] is sold to specialty pharmacies.

(3) Plaintiff's allegations of price fixing between Mallinckrodt and CuraScript are also insufficient to establish an antitrust violation under *Leegin*. The Supreme Court held that vertical

agreements on price would no longer be *per se* unlawful. *Leegin*, 551 U.S. at 889–899, 907. Plaintiff therefore must plead facts making plausible that any alleged price fixing between Mallinckrodt and CuraScript harmed competition in the alleged market for ACTH drugs. *See Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1198 (9th Cir. 2012) (dismissing claim subject to rule of reason analysis, because plaintiff failed to “sketch the outline of the injury to competition with allegations of supporting factual detail”) (internal quotations omitted).

Plaintiff fails to meet its burden. *Leegin* laid out the ways in which a vertical agreement as to price could harm the competitive process: a vertical agreement could (a) “facilitate a manufacturer cartel,” (b) “be used to organize cartels at the retailer level,” or (c) “be abused by a powerful manufacturer or retailer” to either protect the retailer from “innovation in distribution that decreases costs” or “give retailers an incentive not to sell the products of smaller rivals or new entrants.” 551 U.S. at 892–94. Plaintiff does not plead, even in conclusory terms, any such theory. Rather, Plaintiff complains only that the price for Acthar[®] has increased. But “allegations that [a vertical] agreement has the effect of . . . increasing prices to consumers does not sufficiently allege an injury to competition.” *Brantley*, 675 F.3d at 1202 (citing *Leegin*, 551 U.S. at 895–97, and *GTE Sylvania*, 433 U.S. at 55). Plaintiff’s claim should, therefore, be dismissed. *See Spahr v. Leegin Creative Leather Prod., Inc.*, No. 2:07-CV-187, 2008 WL 3914461, at *11 (E.D. Tenn. Aug. 20, 2008) (dismissing claim of vertical price fixing because “plaintiffs allege only that the agreements resulted in higher prices for Brighton products. The Supreme Court made it clear in *Leegin*, however, that higher prices alone. . . are insufficient evidence of anticompetitive effect in the context of a resale price maintenance agreement.”); *Vitacost.com v. Oregon Freeze Dry, Inc.*, No. 09-80367-CIV, 2009 WL 10667820, at *5 (S.D. Fla. July 21, 2009) (same).

c. Plaintiff Fails to Allege Facts Plausibly Showing Non-Speculative Injury Arising From the Synacthen Transaction

Plaintiff also fails to plead a claim for relief based on Questcor’s acquisition of Synacthen because it has not alleged facts making plausible that it has suffered its supposed “antitrust injury” as a result of the transaction. Plaintiff’s theory of antitrust injury is that “but for” the Synacthen transaction, it would have paid a lower price for Acthar[®]. While such an injury would be an antitrust injury if it were adequately pleaded, the violation also must be a “material cause” of any such non-speculative injury. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9, 125-29 (1969); *Van Dyk Research Corp. v. Xerox Corp.*, 631 F.2d 251, 255 (3d Cir. 1980); *Rea v. Ford Motor Co.*, 497 F.2d 577, 589–90 (3d Cir. 1974). Plaintiff has failed to plead any facts making plausible that the Synacthen transaction is a “material cause” of the price it paid for Acthar[®].

The Complaint identifies many steps in the causal chain underpinning Plaintiff’s “but for” world. As Plaintiff admits, the requirements for entry of Synacthen into the U.S. market and a resulting effect on the price for Acthar[®] would include: (1) “sourcing the active pharmaceutical ingredient”; (2) “formulating a sustained-release depot-injection formulation”; (3) “scaling production to clinical scale” (and manufacturing a consistent Synacthen product); (4) “successfully conducting clinical trials necessary for FDA approval”; (5) achieving FDA approval; and (6) marketing Synacthen as an alternative to Acthar[®]. Cmplt. ¶ 482. A new entrant would then also have to gain sufficient acceptance of Synacthen among doctors and TPPs as an alternative therapy to cause Mallinckrodt to lower the price of Acthar. All this would have had to occur *before* the date of Plaintiff’s 2018 payment for Acthar[®]. *Cf. Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 882 (Fed. Cir. 1985) (holding that plaintiff lacked antitrust standing where it was not prepared to enter market until after anticompetitive conduct had ended).

Plaintiff does not allege any facts making this chain of events plausible today, let alone before Plaintiff paid for the Acthar[®] prescription at issue here in 2018.⁷ Indeed, Plaintiff admits that developing Synacthen or another ACTH product that is “stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success.” *Id.* While Plaintiff alleges the two drugs share “similarities,” it admits that they are fundamentally different in that Acthar[®] is a natural ACTH whereas Synacthen is a synthetic. *Compare id.* ¶ 519, *with id.* ¶¶ 228, 556. As such, the two drugs cannot be presumed to have identical effects on the human body. Even assuming *arguendo* that Acthar[®] competes in an “ACTH market,” for Synacthen to be a new entrant to that market and have any plausible effect on the price of Acthar[®] would require completion of all the steps above.

Plaintiff’s failure to allege facts making plausible that all of the steps in this chain of events, including FDA approval for Synacthen, would have occurred by the time of Plaintiff’s purchase of Acthar[®] requires dismissal of its claim. *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 807–08, 815 (D.C. Cir. 2001) (upholding dismissal of an antitrust claim because plaintiff failed to allege facts demonstrating that FDA approval was probable); *Brotech Corp. v. White Eagle Int’l Tech. Grp.*, No. 03-232, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004) (dismissing complaint where plaintiff failed to alleged facts showing timeframe for required FDA approval for product to enter market); *see also Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008) (holding that drug purchaser did not suffer antitrust injury because it failed to show that “but for [the] alleged misuse of [a] patent, the FDA would have granted [a competitor] final approval in February

⁷ In July 2017, Mallinckrodt sublicensed its rights to develop Synacthen for IS and nephrotic syndrome in July 2017. Consent Judgment, *FTC v. Mallinckrodt ARD Inc. et al.*, No. 1:17-cv-00120 (D.D.C. Jan. 18, 2017), ECF No. 2-1. Despite this sublicense, Plaintiff has not alleged that Synacthen now has FDA approval for sale in the United States, nor has it pleaded any facts about the sublicensee’s plans, prospects or schedule to secure FDA approval or its progress in doing so.

2001”); compare *Takeda Pharm. Co. Ltd. v. Zydus Pharm. (USA) Inc.*, 358 F. Supp. 3d 389, 398 (D.N.J. 2018) (holding that plaintiff had alleged antitrust injury by alleging that “the FDA indicated to Zydus that it was prepared to approve Zydus’ [Abbreviated New Drug Application]”).

2. Plaintiff Fails to Allege Facts Plausibly Showing a Relevant Market

Plaintiff’s antitrust claims also all fail for a more fundamental, threshold reason: Plaintiff relies on an implausible proposed relevant antitrust market for only “ACTH drugs,” Cmpl’t. ¶ 470, of which “Acthar[®] has a 100% share of the market,” *id.* ¶ 481. Under any of Plaintiff’s theories, the definition of a “relevant market” is a “critical issue” to establish a violation. *Patel*, 848 A.2d at 830. It is the means by which the Court assesses both whether the alleged conduct harms the competitive process, *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018), and whether Mallinckrodt has sufficient market power to establish a violation, *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 394 (1956). “The relevant product market is defined as those ‘commodities reasonably interchangeable by consumers for the same purposes.’” *Tunis Bros. Co., Inc. v. Ford Motor Co.*, 952 F.2d 715, 722 (3d Cir. 1991) (quoting *E.I. du Pont de Nemours*, 351 U.S. at 395); see also *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962). While the proper product market can be a question of fact: “Where the plaintiff fails to define its proposed relevant market with reference to . . . all interchangeable substitute products . . . , the relevant market is legally insufficient and a motion to dismiss may be granted. *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir.1997) (affirming grant of motion to dismiss). Plaintiff’s proposed market definition does just that.

Indeed, Plaintiff alleges the existence of a variety of cheaper, non-ACTH alternatives for the treatment of certain of Acthar[®]’s approved indications. Cmpl’t. ¶¶ 16 (referencing “less expensive” alternative therapies), 573 (admitting there are “cheaper, effective competitor drugs available to treat certain of Acthar’s approved uses”). Specifically, Plaintiff alleges that

“prednisone is equally efficacious as Acthar, [and] it has the same risks and benefits as Acthar, but at a far cheaper price.” *Id.* ¶ 115. “The same is true of Solu-Medrol (methylprednisone), a synthetic corticosteroid . . . given to people with multiple sclerosis (“MS”) to shorten relapses.” *Id.* ¶ 117. With regard to rheumatoid disorders, for which Plaintiff’s beneficiary was prescribed Acthar®, Plaintiff alleges that “[a] standard treatment for [rheumatoid arthritis (“RA”)] exacerbations includes the administration of steroids, which can be available in brand name or general forms,” and that the “drugs are significantly less expensive than Acthar[®].” *Id.* ¶ 134.

These allegations squarely contradict Plaintiff’s effort to define the relevant market to include only Acthar®; dismissal of its antitrust claims is thus warranted. *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 394 (1956) (“[W]here there are market alternatives that buyers may readily use for their purposes, illegal monopoly does not exist merely because the product said to be monopolized differs from others. If it were not so, only physically identical products would be a part of the market.”); *Queen City Pizza, Inc.*, 124 F.3d at 436 (rejecting, on review of a motion to dismiss, market definition limited to the defendant’s products); *Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 577 (S.D.N.Y. 2011) (dismissing antitrust claims against drug manufacturer because the plaintiff “[did] not plead facts demonstrating that there [were] no other . . . drugs available to treat . . . [premenstrual dysphoric disorder]”); *see also Baar v. Jaguar Land Rover N. Am., LLC*, 295 F. Supp. 3d 460, 465–66 (D.N.J. 2018); *Bldg. Materials Corp. of Am. v. Rotter*, 535 F. Supp. 2d 518, 523–25 (E.D. Pa. 2008).

B. Plaintiff Fails to State Any Claims under the New Jersey RICO Statute (Counts III and IV)

As to its New Jersey RICO claims, Plaintiff fails to plead (i) a pattern of racketeering activity (ii) by a RICO enterprise (iii) causing injury to Plaintiff, each of which is an essential element of its direct RICO claim, *Marina Dist. Dev. Co., LLC v. Ivey*, 216 F. Supp. 3d 426

(D.N.J. 2016), and companion RICO conspiracy claim, *Lum v. Bank of Am.*, 361 F.3d 217, 227 n.5 (3d Cir. 2004).

1. Plaintiff Fails to Allege That Mallinckrodt Participated in a Pattern of Racketeering Activity

Pleading a “pattern of racketeering activity” requires allegations showing “at least two [predicate] acts of racketeering activity.” *Rothberg v. Marger*, No. CIV. 11-5497 RBK/KMW, 2013 WL 1314699, at *10 (D.N.J. Mar. 28, 2013) (Kugler, J.). Here, Plaintiff premises its RICO claim on alleged predicate acts of mail and wire fraud, *see* Cmplt. ¶ 132, which requires Plaintiff to plead, among other things, a “scheme to defraud.” *United States v. Hannigan*, 27 F.3d 890, 892 (3d Cir. 1994). An alleged “scheme to defraud” must include “some sort of fraudulent misrepresentations or omissions reasonably calculated to deceive persons of ordinary prudence and comprehension.” *United States v. Pearlstein*, 576 F.2d 531, 535 (3d Cir. 1978). In addition, “[a] plaintiff who asserts a NJ RICO claim predicated on fraud must comply with Rule 9(b)’s heightened pleading standard.” *Zanger v. Bank of Am., N.A.*, No. CIV. 10-2480 RBK/KMW, 2011 WL 3501867, at *2 (D.N.J. Aug. 10, 2011) (Kugler, J.).

Plaintiff takes a kitchen sink approach, alleging as mail and wire fraud all of the conduct underlying the alleged distribution, pricing, and marketing “schemes.” *See* Cmplt. ¶ 625. Addressing materially identical allegations, the courts in *City of Rockford* and *Washington County Board of Education* recently dismissed plaintiffs’ claims for failure to identify any actionable misrepresentation or omission. *City of Rockford*, 360 F. Supp. 3d at 773–74; *Washington Cty. Bd. of Educ.*, 2020 WL 43016, at *7-12. This Court should do the same.

a. The Alleged Distribution Scheme

The alleged RICO distribution scheme is the same as that underlying Plaintiff’s antitrust claims, Cmplt. ¶ 633, and that which the *Rockford* court previously dismissed under federal RICO,

see 360 F. Supp. 3d at 773–74. Notably, Plaintiff alleges that Questcor publicly disclosed its exclusive distribution agreement with CuraScript in July 2007. *See id.* ¶¶ 153, 163. And Plaintiff does not identify a *single* misrepresentation or omission in connection with that disclosure or the alleged distribution scheme, let alone with the specificity required under Rule 9(b). *See Rockford*, 360 F. Supp. 3d at 773–74.

b. The Alleged Pricing Scheme

Plaintiff also fails to identify a misrepresentation or omission in connection with the principle theory underlying the alleged pricing scheme—that Mallinckrodt misrepresented the price of Acthar® to pharmaceutical publications and in a press release. *First*, although it asserts fraud-based claims subject to Rule 9(b)’s heightened pleading requirements, Plaintiff fails to plead details of the “who, what, when, where and how” of any representation to a pharmaceutical publication, let alone a misrepresentation regarding price.⁸ Plaintiff’s allegations consist solely of sweeping generalities, alleging, for example, that “pharmaceutical industry publications, such as the Red Book and Medispan” for years “set forth the false AWP’s for Acthar, as reported with each price change by Mallinckrodt.” *Id.* ¶¶ 242–43. The conclusory allegation that unspecified AWP’s were “false” does not supply the details necessary to save Plaintiff’s claim from dismissal. *See McCray v. UNITE HERE*, No. CIV. 13-6540 RBK/JS, 2014 WL 3519098, at *5 (D.N.J. July 16, 2014) (Kugler, J.) (“The mere invocation of predicate acts in a complaint is insufficient to plead a claim for civil RICO.”). Plaintiff’s invocation of *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20 (D. Mass. 2007), is inapposite. Unlike in that case, Plaintiff here does not allege any misleading “spread” between the price it charges CuraScript and

⁸ For these reasons, the remaining components of the alleged pricing scheme—purported price fixing and Questcor’s acquisition of Synacthen—must be dismissed for failure to allege a misrepresentation or actionable omission.

the AWP price paid by third party payors. Rather, Plaintiff alleges that “[l]ike other brand name, injectable drug manufacturers, Mallinckrodt adopted a 25% markup factor for its AWP for Acthar,” *i.e.*, “once Mallinckrodt sets a new [wholesale acquisition cost (“WAC”)], the AWP is calculated at 25% above the new WAC.” Cmplt. ¶ 210. Accordingly, the stated AWP is not false or misleading. *See Washington Cty. Bd. of Educ.*, 2020 WL 43016, at *9.

Second, Plaintiff fails to allege sufficient facts showing that a 2018 press release issued by the Mallinckrodt CEO Mark Trudeau claiming the price of Acthar® “today is \$38,892,” Cmplt. ¶ 238, was inaccurate. And even if there were some basis to find that the price was factually inaccurate, this allegation could not support a claim by Plaintiff, which alleges that it paid over \$10,000 *less* than the price quoted in the press release. *See id.* ¶ 29 (alleging Plaintiff paid \$26,100.28 for Acthar®).

Third, Plaintiff’s allegation that Mallinckrodt “conceal[ed] the truth” about the “real reasons for the exorbitant price increases,” *id.* ¶ 222, is not an actionable omission. Essential to pleading any fraudulent omission is alleging facts that would show the speaker’s “intent that the other party relies on it.” *Jatras v. Bank of Am. Corp.*, No. CIV. 09-3107 RBK KMW, 2010 WL 5418912, at *5 (D.N.J. Dec. 23, 2010) (Kugler, J.). Plaintiff does not allege that Mallinckrodt disclosed *any* reasons for its prices—let alone allege facts that would show its disclosed reasons implied an intent to induce reliance by TPPs. Any such “omission” is not actionable. *See id.*; *see also Washington Cty. Bd. of Educ.*, 2020 WL 43016, at *8 (“If this obligation [to disclose the motives behind otherwise public conduct] did exist, it seems a company might be required to disclose its profit-seeking motive every time it publicly raised the price of its product.”).

c. The Alleged Marketing Scheme

Plaintiff asserts three theories in support of the alleged marketing scheme: (1) allegations that Mallinckrodt KOLs and MSLs marketed Acthar for “off-label” uses, Cmplt. ¶¶ 20, 266–70, 272–74; (2) payments to doctors that Plaintiff alleges were bribes meant to induce those doctors to prescribe Acthar®, *id.* ¶¶ 15, 388, 426; and (3) the PAP *see id.* ¶¶ 15, 379. None contains an actionable misrepresentation or omission.

First, while Plaintiff premises its “off-label” marketing allegations on a *qui tam* complaint, *see id.* ¶ 11, that action related specifically to the promotion of Acthar® to neurologists for use in the treatment of MS. *See generally United States ex rel. Strunck. v. Mallinckrodt ARD LLC*, 12-cv-00175 (E.D. Pa. June 13, 2017), Dkt. 40. The unproved allegations in the *qui tam* complaint have nothing to do with Plaintiff’s claim that it paid too much for the Acthar® at issue here, which was prescribed to treat a rheumatoid disorder. *See id.* ¶¶ 111, 357. Plaintiff alleges that KOLs and MSL’s delivered “false, misleading and deceptive promotional messages about the mode of action, safety, efficacy and value of Achar,” Cmplt. ¶ 20, but fails to identify a specific misrepresentation by a KOL or MSL in New Jersey or the “the who, what, when, where and how” of such misrepresentation, *see id.* ¶¶ 266–70, 272–74. Plaintiff’s failure mandates dismissal. *See Washington Cty. Bd. of Educ.*, 2020 WL 43016, at *11; *see also, e.g., Southward v. Elizabeth Board of Education*, 2017 WL 111924, at *17 (D.N.J. 2017) (dismissing New Jersey RICO claim where “the who, what, when, where, and how” were “largely absent”).

Second, even if Plaintiff alleged with specificity sufficient to show that payments to doctors were bribes or kickbacks (it has not), *see* Cmplt. ¶¶ 15, 388, 426, Plaintiff identifies no misrepresentation in connection with such allegations. And “Plaintiff does not allege that Mallinckrodt made any representations about how it would promote Acthar®, so failing to disclose

that it paid a kickback was an omission, but not necessarily deceptive one.” *Washington Cty. Bd. of Educ.*, 2020 WL 43016, at *12. *Third*, Plaintiff has likewise failed to allege any misrepresentation or omission in connection with copay assistance for Acthar®.

2. Plaintiff Fails to Allege Facts That Would Show a RICO Enterprise

“[E]nterprise” is an element distinct from the incidents constituting the “pattern of racketeering activity,” and the existence of both must be alleged in order to establish a RICO violation. *State v. Ball*, 661 A.2d 251, 261 (N.J. 1995). To properly plead a RICO enterprise, a plaintiff must allege “a shared purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise’s purpose.” *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 370 (3d Cir. 2010) (citation omitted).

Here, Plaintiff alleges there is an “Acthar Marketing Enterprise, an association in fact,” Cmplt. ¶ 622, and concludes that Defendants “associated together for the common purpose of promoting Acthar for off-label uses and doses, and earning profits therefrom,” Cmplt. ¶ 623. But Plaintiff offers no facts plausibly showing that the supposed participants—“(i) Mallinckrodt, and its MSLs and sales representatives, (ii) Cigna/Express Scripts and its subsidiaries, including UBC and its [reimbursement specialists], Accredo and its pharmacists, and CuraScript and its employees, (iii) sales representatives like Pratta, and (iv) KOLs, both named and unnamed in this Complaint,” *id.* ¶ 622—actually shared this alleged purpose, or that the alleged racketeering activity was conducted through any such enterprise. Only facts, not “bald assertions,” and “legal conclusions” are assumed true. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d at 906. And allegations of “run of the mill” business activities do not establish a RICO enterprise. *See Bolick v. Ne. Indus. Servs. Corp.*, 2015 WL 540066, at *12 (M.D. Pa. Feb. 10, 2015) (dismissing RICO

claims); *Barbieri v. Wells Fargo & Co.*, 2014 WL 7330461, at *6 (E.D. Pa. Dec. 22, 2014) (similar). The Complaint contains allegations of nothing more.

3. Plaintiff Fails to Allege RICO Injury or Causation

Plaintiff's bare allegation that it "overpaid thousands of dollars in inflated reimbursements" for Acthar®, Cmplt. ¶ 637, reveals the wide chasm between its purported injury and the alleged predicate acts it claims constitute the alleged marketing scheme. Under federal and New Jersey law, a RICO violation must be both the "but for" and proximate cause of injury. *See Holmes v. Sec. Investor. Prot. Corp.*, 503 U.S. 258, 268 (1992); *Interchange State Bank v. Veglia*, 668 A.2d 465, 472 (N.J. Super. Ct. App. Div. 1995). Plaintiff has not pleaded either form of causation.

Plaintiff fails to allege any "but for" connection between Mallinckrodt's alleged conduct and Plaintiff's alleged harm. *First*, Plaintiff premises marketing claims on "off-label" promotion, Cmplt. ¶¶ 20, 266–70, 272–74, but does not even allege that the prescription it paid for was written for an "off-label" indication. Plaintiff alleges it paid for a single prescription written for a rheumatic disorder, *id.* ¶¶ 111, 357, and Acthar® is approved as adjunctive therapy for short term administration in several rheumatic disorders, including rheumatoid arthritis, *id.* ¶¶ 18, 111, 120, 380; Ex. A. *Second*, Plaintiff's claims include allegations premised on fraud arising from alleged bribery or kickbacks, *id.* ¶¶ 15, 388, 426, but Plaintiff does not identify the doctor who prescribed Acthar to its beneficiary, let alone identify a payment to such doctor or the timing or other details of such payment. *Third*, Plaintiff does not allege that its plan required its beneficiary to pay a co-payment, or that the beneficiary received assistance from a "patient assistance program."⁹ Absent

⁹ Tellingly, Plaintiff's PAP allegations are premised on the United States Complaint in Intervention, No. 2:13-cv-01776-BMS, ECF No. 57, in the *qui tam* actions, which expressly alleges that "[i]n December 2013, CDF decided to close Mallinckrodt's funds," though "Mallinckrodt continued to subsidize Acthar copays using CDF through 2014." *Id.* ¶ 154. That

such allegations, Plaintiff cannot claim any injury, let alone an injury that occurred “as a result of” any conduct by Mallinckrodt. *Southward*, 2017 WL 4392038, at *12.

Even if Plaintiff could allege facts showing “but for” causation, the causal chain connecting the alleged conduct and alleged harm would be too attenuated to establish proximate causation a matter of law. To assess the sufficiency of allegations that “a racketeering act is the proximate cause of a plaintiff’s injury, a court must examine the [alleged] chain of events to determine if the plaintiff [pleads it] was directly injured by the predicate acts.” *Fagan v. Fischer*, 2016 WL 347318, *14 (D.N.J., 2016). Courts routinely reject RICO claims analogous to those asserted here, concluding that independent decisions between promotion and payment preclude a payor like Plaintiff from recovering under RICO. *See, e.g., Sidney Hillman Health Ctr. v. Abbott Labs.*, 873 F.3d 574, 578 (7th Cir. 2017) (holding that “improper representations made to physicians do not support a RICO claim by Payors, several levels removed in the causal sequence”).¹⁰

Plaintiff’s allegations reveal the significant contingent steps that must occur before it reimburses for Acthar®, which necessarily interrupt causation. The ASAP program requires every patient and health care provider to fill out and sign the Acthar Start Form prior to receiving Acthar®. *See* Cmplt. ¶¶ 184, 409. A physician must determine that Acthar® is “medically necessary” before the medication ships. *Id.* ¶ 545. “[T]he patient authorizes Mallinckrodt and UBC, its ‘Designated operator’, to provide certain services to [the patient], including reimbursement and coverage support.” *Id.* ¶ 189. UBC “confirms the patient’s insurance coverage

is, the complaint alleges conduct ending in **2014** (*id.* ¶ 2)—at a minimum of three years before Plaintiff alleges it paid for an Acthar® prescription in 2018 (Cmplt. ¶ 106).

¹⁰ In contrast, the Third Circuit, in *In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633, 642 (3d Cir. 2015), allowed the RICO claims based on alleged misrepresentations about the safety of the drug to proceed to discovery because the court concluded that misrepresentations as to the health risks of Avandia “caused TPPs and PBMs to place Avandia in the formulary.” *Id.* at 644. There is no such allegation in the Complaint.

or other source of payment . . . [and] then arranges for the Acthar to be delivered directly to the patient by CuraScript.” *Id.* ¶ 185. Notably, Plaintiff alleges that Express Scripts’ 2018 Prior Authorization Policy reflects its 2017 recommendation **not** to recommend prescribing Acthar® for indications other than IS and MS. *See id.* ¶ 297. Plaintiff’s alleged harm is too remote.

C. Plaintiff’s Fails to State a Claim under the New Jersey Consumer Fraud Act (Count I)

Plaintiff’s CFA claim must be dismissed for several reasons. As a threshold matter, Plaintiff’s CFA claim fails because, as a third-party payor that did not itself use Acthar®, *Cmpl.* ¶¶ 29, 111, Plaintiff lacks standing to pursue a claim under the Act, *MSP Recovery Claims, Series, LLC v. Sanofi Aventis U.S. LLC*, No. 3:18-CV-2211-BRM-LHG, 2019 WL 1418129, at *18 (D.N.J. Mar. 29, 2019) (dismissing claim because plaintiff’s assignors “do not use or consume the prescriptions but are third-party middlemen payors”); *Cent. Reg’l Emp. Benefit Fund v. Cephalon, Inc.*, Civ. A. No. 09-3418, 2009 WL 3245485, at *3 (D.N.J. Oct. 7, 2009) (same); *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 WL 2043604, at 32 (D.N.J. Jul. 10, 2009) (same).

Plaintiff’s CFA claim also fails for the same basic reasons its RICO claim fails. Like the RICO claim, the CFA claim must be premised on a false or misleading practice, *Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 503 (D.N.J. 2006), identified with the particularity required by Rule 9(b), *Feingold v. Graff*, 516 F. App’x 223, 226 (3d Cir. 2013). Yet Plaintiff fails to so identify any supposed false statement.¹¹ And, as under RICO, Plaintiff must identify an

¹¹ Plaintiff’s effort to base its CFA claim on allegations of anticompetitive conduct do not alter the requirement that it identify a misrepresentation. *See Island Mortg. of New Jersey & Perennial Lawn Care, Inc. v. 3M*, 373 N.J. Super. 172, 177, 860 A.2d 1013, 1018 (Law. Div. 2004) (holding that establishing a violation of antitrust law does not establish a violation of the CFA); *Sickles v. Cabot Corp.*, 379 N.J. Super. 100, 117, 877 A.2d 267, 277 (App. Div. 2005) (same).

ascertainable loss caused by the alleged conduct. *Bosland v. Warnock Dodge, Inc.*, 197 N.J. 543, 558 (2009). Yet Plaintiff does not contend that the Acthar[®] prescriptions it covered were medically unnecessary or harmful. Moreover, the learned intermediary doctrine defeats causation under the CFA. *New Jersey Citizen Action v. Schering-Plough Corp.*, 367 N.J. Super. 8, 14, 842 A.2d 174, 178 (App. Div. 2003) (dismissing CFA claim under learned intermediary doctrine).

More fundamentally, the CFA does not apply where other “sources of regulation deal specifically, concretely, and pervasively with the particular activity, implying legislative intent not to subject parties to multiple regulations that, as applied, will work at cross-purposes.” *Lemelledo v. Beneficial Mgmt. Corp. of Am.*, 150 N.J. 255, 270 (1997). The CFA was not intended to address “a heavily regulated industry when application of [the CFA] would create a ‘real possibility’ of conflict between the directives of the [CFA], as administered by the Division of Consumer Affairs, and the directives of the regulatory schemes of other administrative bodies.” *Doug Grant, Inc. v. Greate Bay Casino Corp.*, 3 F. Supp. 2d 518, 536 (D.N.J. 1998) (citing *Lemelledo*, 150 N.J. at 271), *aff’d as modified and remanded*, 232 F.3d 173 (3d Cir. 2000). The risks of such conflict are conspicuous here, where the Complaint contains extensive allegations concerning FDA regulation of Acthar, including those concerning “off-label” marketing. *See, e.g.*, Cmpl’t. ¶¶ 44–73.

D. Plaintiff Fails to State any Common-Law Claims (Counts V-VIII)

Plaintiff’s negligent misrepresentation claim is also premised on the same allegations, and suffers from the same basic failures, as its deficient RICO allegations. *See supra* Part IV.B.; *Wyndham Hotels & Resorts, LLC v. Northstar Mt. Olive, LLC*, No. CIV. 10-2583 RBK/AMD, 2013 WL 1314747, at *11–12 (D.N.J. Mar. 28, 2013) (specifying facts needed to plead a duty to disclose and render an omission actionable). Plaintiff must allege “[t]he actual receipt and consideration of any misstatement” to plead a negligent representation claim, *Kaufman v. i-Stat Corp.*, 165 N.J. 94, 109, 754 A.2d 1188, 1195 (2000). Plaintiff instead expressly disclaims

knowledge of any false statement when it alleges that “Local 322 was harmed in that *it was unaware* of the artificial, inflated prices of Acthar, would not have paid and/or reimbursed the artificially inflated prices for Acthar *had it known of the false representations . . .*” Cmpl. ¶ 665 (emphasis added).

The conspiracy/aiding and abetting claim requires Plaintiff to plead that the “principal performed an unlawful act.” *Delzotti v. Morris*, No. 14-7223, 2015 WL 5306215, at *8 (D.N.J. Sept. 10, 2015). Plaintiff’s failure to do so here requires dismissal. *See, e.g., McMullin v. Casaburi*, No. A-3411-16T3, 2018 WL 3673256, at *5 (N.J. Super. Ct. App. Div. Aug. 3, 2018).

Plaintiff’s unjust enrichment claim must be dismissed because “New Jersey does not recognize unjust enrichment as an independent tort cause of action.” *Warma Witter Kreisler, Inc. v. Samsung Elecs. Am., Inc.*, No. CIV. 08-5380 (JLL), 2009 WL 4730187, *7 (D.N.J. Dec. 3, 2009) (citation omitted). Plaintiff also fails to plead unjust enrichment as a basis for quasi-contractual liability because it fails to allege facts that show that Mallinckrodt “received a benefit and that retention of that benefit without payment would be unjust,” or that Plaintiff “expected remuneration from [Mallinckrodt] at the time it performed or conferred a benefit” on Mallinckrodt. *VRG Corp. v. GKN Realty Corp.*, 135 N.J. 539, 554 (1994); *see also Equiom (Isle of Man) Ltd. v. Jacobs*, No. 16-4362, 2017 WL 6550481, at *4 (D.N.J. Dec. 22, 2017). Nor could it, as Plaintiff does not allege that it made any purchases directly from Mallinckrodt. *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 711 (D.N.J. 2011) (dismissing unjust enrichment claim for lack of “a sufficiently direct relationship” with the defendant manufacturer).

V. CONCLUSION

For the above reasons, the Court should dismiss Plaintiff’s Complaint in its entirety with prejudice.

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